

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS**

UNITED STATES OF AMERICA,

v.

KINGSLEY R. CHIN,
ADITYA HUMAD, and
SPINEFRONTIER, INC.,

Defendants.

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) Criminal No. 1:21-cr-10256-IT
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DEFENDANTS' MOTION TO COMPEL CMS RECORDS

Defendants Kingsley R. Chin, Aditya Humad, and SpineFrontier, Inc. respectfully submit this motion to compel the production of records from the Centers for Medicare and Medicaid Services ("CMS") concerning SpineFrontier. As described below the government previously represented to the Court there was no live dispute about the production of these documents and then made representations to defense counsel that they had completed the production, only to admit later in response to pointed questions that reasonably expected formal collection efforts did not actually take place.

Prior to the last hearing, Defendants had requested that the government produce records of CMS concerning SpineFrontier. Specifically, during written portions of meet and confer efforts, defendants requested, among other things, documents concerning SpineFrontier's reporting under the Sunshine Act, Error and Warning Codes, Review and Dispute Data, Review and Correct Data, Data Displays, communications among various stakeholders during these processes; documents sufficient to identify government employees who are witnesses to communications about SpineFrontier's reports of payments; and all other communications and data tending to show compliance by SpineFrontier.

At the hearing on March 28, 2024, the government agreed to collect this information from CMS (a federal agency and its own “client” in the related civil case), which is critical to the defendants’ preparation of a defense. The Court questioned counsel about whether there was a live dispute, to which defense counsel responded: “Yes, Your Honor. The – it’s a live dispute. The government has obtained selectively some materials from CMS, produced those, but not generally.” Tr. of 3/28/24 Hrg. at 18. Representing to the Court that it would comply with the document request, the government then responded: “There is no dispute here” because “we have now agreed, notwithstanding our legal position that we’re not required to do so, to go to CMS and request the information they’ve asked for,” and “we will be producing more information from CMS. So on this, I do not believe there is a live dispute.” *Id.* Based on the government’s representation, the Court invited a follow-up motion by the defense to compel the production of CMS records concerning SpineFrontier if the Defendants believed something was missing. *Id.*

On or about July 9, 2024, the government produced additional documents to defendants, accompanied by a cover letter that indicated in substance that the government had completed its work and “produced to you the responsive information we received from CMS.” After reviewing the limited materials, defense counsel inquired about the collection process and suggested a possible motion to compel. The government refused to identify how or with whom prosecutors worked at CMS to collect and produce responsive documents. In an email dated July 17, 2024, the government reaffirmed, albeit vaguely, the completeness of the production and claimed an inability to understand questions about anything else that could be done to collect and produce responsive documents, stating:

As we told you in our July 9 letter, we requested from CMS the information you specifically asked for, *i.e.*, information and materials “concerning Error and Warning Codes, Review and Dispute Data, Review and Correct Data, Data Displays, and communications among various stakeholders during these

processes” and all “communications and data tending to show compliance by SpineFrontier,” with the Sunshine Act. See Def.’s Dec. 22, 2023 Ltr. at 2. We also followed up with CMS and made a broader request, as you requested in your December 22 Letter, for “all communications and data tending to show compliance by SpineFrontier,” with the Sunshine Act. See also Gov’t July 9, 2024 Ltr. at 1. We have produced what CMS provided in response. We do not understand the basis for your reference to a “further requirement to collect and produce CMS materials.”

Accordingly, in a series of communications, the government made it seem as if it had engaged in a genuine collection and production process. When pressed further, however, the government’s position collapsed. In the end, the government refused to describe the collection and production process without more from the defense, now referring to CMS as a “third party” that would have conducted any collection on its own.

Contrary to the government’s representations to the Court and to defense counsel, there is a live dispute and the government’s production of critical CMS records concerning SpineFrontier remains glaringly deficient. The July 9 production did not even respond to the specific categorical requests for CMS documents about SpineFrontier’s disclosures. The July 9 production included some documents relating to the “CMS-Open Payments Program,” including self-serving audit reports seemingly prepared by CMS in furtherance of the investigation underlying this prosecution, and documents relating to a witness, Dr. Joseph Shehadi. Specifically, the government’s recent correspondence suggests that, when producing these limited materials, it treated CMS entirely as a third party from which it could selectively gather materials after making vague requests to an unidentified CMS worker, rather than genuinely collecting and producing materials responsive to each of the categories of CMS’s documents about SpineFrontier that Defendants had requested.

The Memorandum and Order dated July 3, 2024, addressed the government’s agreement to gather and produce these CMS records and recognized Defendants’ argument at that time as

raising a *Brady* issue in anticipation of an incomplete production. *See* Memorandum and Order at 11. Now the government’s position in correspondence and the limited scope of the production confirm the incompleteness of the production contrary to its representations and express agreement before this Court to produce responsive materials.

With respect to materiality of the materials, CMS has been inextricably intertwined with the investigation into and the subject of this prosecution and related civil claims against SpineFrontier. Recently-produced documents show that CMS played a key role in connection with audits of SpineFrontier underlying and relating to the pending charges. Furthermore, the Amended Complaint in the related civil action reflects how central CMS has been to the subject matter of this action. The Amended Complaint by the relator (*United States of America v. SpineFrontier, Inc. et al.*, Case 1:15-cv-12908, Doc. 112) states in pertinent part about CMS, among other things, the following:

- Paragraph 27: Plaintiff **United States of America is acting on behalf** of the United States Department of Health and Human Services (“HHS”) and the **Centers for Medicare and Medicaid Services (“CMS”)**, which administers the Health Insurance Program for the Aged and Disabled established by Title XVIII of the Social Security Act, 42 U.S.C. § 1395, et seq. (“Medicare”)....
- Paragraph 64: the **Physician Payments Sunshine Act (“PPSA” or “Sunshine Act,” a/k/a “Open Payments program”)** was enacted at or about this time, requiring **medical device manufacturers to disclose to CMS any payments or other transfers of value made to physicians** or teaching hospitals. Under the “Sunshine Act”, a covered manufacturer (such as SpineFrontier) became obligated to disclose to CMS any payment or transfer of value made to a physician or hospital, as well as any physician ownership or investment in the covered manufacturer.
- Paragraph 125: ... **[N]one of the Consultant fees paid by IME are reflected in the database created as part of the Sunshine Act** and as required by that law. Defendants were required to report, by March 31, 2014, such payments or transfers of value for the last five months of 2013, the first reporting cycle, and by March 31, 2015, for payments or transfers of value during the year 2014, the second reporting cycle. **Defendants did not comply with these requirements. By avoiding compliance with the Sunshine Act, which would have disclosed Defendants’ financial arrangements with IME**

Consultants, Defendants sought to avoid liability under the False Claims Act, the Stark Law, and the Anti-Kickback statute.

- Paragraph 274: Specifically, **the Physician Payments Sunshine Act (“PPSA” or “Sunshine Act”)** – also known as section 6002 of the Affordable Care Act (ACA) of 2010 – **requires medical device manufacturers to disclose to CMS any payments or other transfers of value made to physicians** or teaching hospitals.
- Paragraph 275: As of August 1, 2013, **a covered manufacturer (such as SpineFrontier) must disclose to CMS any payment or transfer of value made to a physician** or hospital, as well as any physician ownership or investment in the covered manufacturer.
- Paragraph 284: **Reimbursement for Medicare claims is made by the United States through CMS** which contracts with private insurance carriers to administer and pay claims from the Medicare Trust Fund. 42 U.S.C. § 1395u. In this capacity, the carriers act on behalf of CMS.

(Emphasis added).

In the Complaint in Intervention by the government in the related civil action, similar allegations reflect the critical role of CMS in this case:

- Paragraph 27: As of August 1, 2013, **a covered manufacturer (such as SpineFrontier) must disclose to CMS any payment or transfer of value made to a physician** or hospital, as well as any physician ownership or investment in the covered manufacturer.
- Paragraph 31: **CMS, an agency of HHS, administers the Medicare program.**

It is difficult to fathom that the government can use CMS as a sword and shield here, selectively choosing what it has collected from the agency and what it claims is merely held by a third party, when in fact the prosecution team has possessed and exploited a clear ability to access CMS materials. Even worse, the government’s representations to the Court and initial communications with defense counsel misled defense counsel into believing that the government would have engaged in a genuine collection and production process, rather than a vague or selective request from an unidentifiable CMS worker.

Despite multiple requests and conferrals, the government’s representations to the Court and defense counsel, and the government’s agreement on the record that it would produce

responsive materials from CMS concerning SpineFrontier, the government has not genuinely collected and produced the CMS records concerning SpineFrontier that were requested. Trial is rapidly approaching, and Defendants expect they may retain expert witnesses related to the anticipated materials. The government's delay is interfering with Defendants' preparation for trial.

CONCLUSION

Based on the foregoing, this Court should compel the government to produce all CMS records and data concerning SpineFrontier as requested by the defense when the government represented to the Court there was no dispute on these issues. The requests for documents at issue included (1) documents concerning reporting under the Sunshine Act, Error and Warning Codes, Review and Dispute Data, Review and Correct Data, Data Displays, (2) communications among various stakeholders during these processes; documents sufficient to identify government employees who are witnesses to communications about SpineFrontier's reports of payments; and (3) all other communications and data tending to show compliance by SpineFrontier.

Respectfully submitted,

**KINGSLEY CHIN and
SPINEFRONTIER, INC.**

By their attorneys,

/s/ Barry S. Pollack

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Local Rule 7.1(a)(2) Certification

As described above, defense counsel attempted in good faith to confer with counsel for the government in an effort to resolve or narrow the issues described herein during a series of correspondence set forth above. The government stated that it would oppose this motion.

/s/ Barry S. Pollack

Certificate of Service

The undersigned certifies that this document, filed through the ECF system, will be electronically served on counsel who are registered users of ECF on July 26, 2024.

/s/ Barry S. Pollack